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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,678	12/08/2003	Benjamin Oshlack	006750-0264-999	4265

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EXAMINER	
FITZGERALD, MARC C	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 01/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/731,678	OSHLACK ET AL.	
	Examiner	Art Unit	
	Marc C. Fitzgerald	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *80-106* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *80-106* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *04/06/04; 04/26/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

Receipt is acknowledged of correspondences received on 6 May 2004 in the matter of U.S. Patent Application No. 10/731,678. Claims included in the prosecution are 80-106.

Nonstatutory Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 80-106 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17, 19-26, and 28-66 of U.S. Patent No. 5,965,161 in view of *Remington: The Science and Practice of Pharmacy, Nineteenth Ed.* Although the conflicting claims are not identical, they are not patentably

distinct from each other. The reference teaches a sustained-release oral dosage form in the form of a tablet or capsule comprising an opioid analgesic, i.e., oxymorphone, alkylcellulose, a binder, and diluent (column 1, lines 1-10; column 4, lines18-23). The instant application specifically claims the species ethylcellulose in claims 83 and 95 whereas the reference recites the broader use of hydroxyalkylcellulose in claim 8. It would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of alkylcellulose, including those of the instant claims, because the artisan would have the reasonable expectation that any of the species of the genus would have similar properties and, thus the same use a the genus as a whole. Support for this expectation may be found in *Remington: The Science and Practice of Pharmacy, Nineteenth Ed.*, p. 1617 which teaches ethy cellulose as a suitable binder in tablet formulations. Thus a recitation of the genus in the prior art reference obviates the claims enumerated in the instant claim set.

Claims Rejection(s) – 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 80-106 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,472,712 to Oshlack et al. ('712) in view of U.S. Patent No. 4,464,378 to Hussain ('378).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

It is recognized that applicants are claiming the benefits of many copending applications. The effective filing date of the instant application is 10/07/93. There is no sufficient support for oxymorphone in U.S. Patent No. 5,472,712 which is a CIP of 08/133,503 having the filing date of 10/07/93. Therefor U.S. Patent 5,472,712 is a competent reference.

'712 teaches a controlled-release formulation and a method of treatment comprising an opioid analgesic, ethyl cellulose, binder, and diluent (Abstract, column 2, lines 60-66; column 3, lines 40-41, column 15, lines 1-2, column 40, line 60). According to the patent, the formulation may be formed into a tablet or capsule which provides a therapeutic effect for about 12 hours to 24 hours (column 2, lines 60-62, column 4, line 61, column 5, line 20, column 6, lines 20-29). The patent also teaches that the granules used to make the oral dosage forms have a diameter of between 0.2 mm and 2.5 mm, with a preferred range of 0.5 to 2 mm (column 9, lines 36-37). The range taught in the

patent would read on the particle size range taught in the instant application of 0.1 mm to about 3 mm. The working examples in the patent cite the use of hydromorphone as the opioid analgesic.

The instant claims differ from the reference by reciting a specific species which is oxymorphone. '378 teaches a controlled drug formulation wherein hydromorphone and oxymorphone are taught as equivalent species (column 3, lines 10-14). Therefore at the time of the invention, one of ordinary skill in the art would have been motivated to substitute hydromorphone with oxymorphone with the reasonable expectation that any of the species of the genus would have similar properties and thus render success. Hence, U.S. Patent No. 5,472,712 in view of U.S. Patent No. 4,464,378 obviates the claims enumerated in the instant application.

Pertinent Art(s)

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: U.S. Patent 5,099,030 to Gardner et al. The art is cited of interest because it teaches sustained release tablet and capsule and method of making comprising an opioid analgesic, ethyl cellulose, a binder and diluent.

Correspondences

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marc C. Fitzgerald whose telephone number is (571) 272-8510. The examiner can normally be reached between 7:30 AM - 4:00 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marc C. Fitzgerald
Art Unit –1615

12 January 2006

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600